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1272230

# THE UNITED STATES OF AMERICA

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***January 11, 2005***

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**APPLICATION NUMBER:** ***60/529,357***
**FILING DATE:** ***December 12, 2003***
**RELATED PCT APPLICATION NUMBER:** ***PCT/US04/41694***

Certified By

Jon W Dudas

Under Secretary
of Commerce for Intellectual Property
and Acting Director of the
Unites States Patent and Trademark Office

PTO/SB/16 (05-03)
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# *PROVISIONAL APPLICATION FOR PATENT COVER SHEET*

**This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53(c).**

**Express Mail Label No.** EF158337046US

## INVENTOR(S)

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*Additional inventors are being named on the* 1 *separately numbered sheets attached hereto*

## TITLE OF THE INVENTION (500 characters max)

SYSTEM AND METHOD FOR OPTIMIZING CLINICAL OPTIC PRESCRIPTIONS

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## ENCLOSED APPLICATION PARTS *(check all that apply)*

☑ Specification *Number of Pages* 48
☐ CD(s), Number
☑ Drawing(s) *Number of Sheets* 5
☑ Other (specify) Check for $80.00; Return Postcard Declaration and Power of Attorney for Inventors
☐ Application Data Sheet. See 37 CFR 1.76

## METHOD OF PAYMENT OF FILING FEES FOR THIS PROVISIONAL APPLICATION FOR PATENT

☑ Applicant claims small entity status. See 37 CFR 1.27.
☑ A check or money order is enclosed to cover the filing fees.
☑ The Director is hereby authorized to charge filing fees or credit any overpayment to Deposit Account Number: 09-0007
☐ Payment by credit card. Form PTO-2038 is attached.

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☑ No.
☐ Yes, the name of the U.S. Government agency and the Government contract number are: ______________________



*Respectfully submitted,*

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Date 12/12/03

REGISTRATION NO. (*If appropriate*) 35,167

Docket Number: P00873-US-00+

## *USE ONLY FOR FILING A PROVISIONAL APPLICATION FOR PATENT*

# *PROVISIONAL APPLICATION COVER SHEET*
## *Additional Page*



Docket Number P00873-US-00+

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Number 2 of 2

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# Provisional Patent Application

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SYSTEM AND METHOD FOR OPTIMIZING
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## Abstract of the Disclosure

An expert method and system for determining the appropriate refractive prescription in a clinical optometry or ophthalmology setting. Data in the form of aberrometric input, patient history and other information, and/or other environmental data is used to optimize a real-world prescription for an individual's optic needs.

## Field of the Invention

This invention relates to the field of optics, and particularly to the field of ocular corrective optics.

## Background of the Invention

The purpose of a conventional, ophthalmic refraction of the eye is to determine that combination of spherical and cylindrical lenses which optimizes visual acuity for distant objects. The underlying assumption of refraction is that visual acuity is maximized when the quality of the retinal image is maximized. Furthermore, it is commonly assumed that retinal image quality is maximized when the image is optimally focused. For these reasons, the endpoint of a subjective refraction is taken as an operational definition of the term "best focus" as applied to eyes.

Rapid commercialization of aberrometers makes it as easy to measure the eye's higher order aberrations with a clinical aberrometer as it is to measure the lower-order, sphero-cylindrical aberrations with an autorefractor. These modern clinical aberrometers employ either a Shack-Hartmann wavefront-sensing technique or subjective ray-tracing technique that provides detailed maps of the eye's refracting properties across the entire pupil. Such aberration maps

have the potential to be "prescriptions for perfection" that form the basis of wavefront-guided refractive surgery and contact lens design.

Although the wavefront aberrations function is a fundamental description of the eye's optical imperfections, detailed aberration maps contain a wealth of information that can overwhelm its interpretation. One way to reduce the dimensionality of an aberration map is to fit the map with a relatively small number of Zernike radial polynomials. Reducing a detailed aberration map to a spectrum of Zernike coefficients simplifies the description, but a Zernike spectrum remains a complex description and its relationship to visual quality is complicated. The ultimate reduction of dimensionality is a single number, such as RMS wavefront error, that represents an overall metric of image quality. Such a reduction is desirable.

Aberrometers measure all of the eye's monochromatic aberrations and display the result in the form of an aberration map. Since the second order aberrations of astigmatism and defocus are included in this map, an obvious strategy is to prescribe the correcting lens that eliminates second-order aberrations. Unfortunately, the problem is not solved so easily. Several studies have shown that eliminating the second-order Zernike aberrations does not necessarily optimize the subjective impression of best-focus nor the objective measurement of visual performance (Applegate, Ballentine, Gross, Sarver, & Sarver, 2003; Guirao & Williams, 2003; Thibos, Hong, Bradley, & Cheng, 2002 incorporated by reference herein).

Eliminating second-order Zernike aberrations is equivalent to minimizing the root mean squared (RMS) wavefront error, but this minimization does not necessarily optimize the quality of the retinal image. Another problem is the lack of a universally-accepted metric of image quality that could be used to establish objectively the state of optimum-focus for an aberrated eye. A useful metric of optical quality for the human eye is one that is highly correlated with

visual performance, the subjective judgment of best focus, or other tasks that are optically limited. Although standard metrics such as Strehl ratio and RMS are in widespread use in the world of ophthalmic optics, they are better suited for describing optical systems that have much higher quality (i.e. are closer to diffraction-limited) than the typical eye. Indeed, recent data suggests that RMS wavefront error and calculations based on RMS error such as equivalent defocus are poor predictors of visual acuity for aberrated retinal images. Therefore, there is a need to identify metrics which are good indicators of visual acuity for aberrated retinal images. Thus a search has begun for alternative metrics of optical quality that are optimized by subjective refraction. This search indicates that there is a need for a metric or metrics which may best optimize subjective refraction.

Assuming that consensus agreement could be achieved for a metric of choice, one still needs to deal with the fact that the condition of "best focus" is a multi-dimensional problem in optimization. U.S. patent number 6,511,180 to Guirao & Williams (which is hereby incorporated by reference) described an iterative method for finding the optimum sphere, cylinder and axis parameters by simultaneously optimizing a metric of image quality. However, such a method requires a great deal of computing power to perform, and may not optimize the optical acuity. Other possibilities include an objective version of the clinical technique of refraction by successive elimination. A first approximation would eliminate the bulk of defocus error by correcting the eye with a spherical lens of power $M$, the so-called "spherical equivalent". Next, the eye's astigmatism is corrected with a cylindrical lens, followed by a fine-tuning of the spherical lens power. This is the basis of some of the methods described herein.

A variety of other problems must be solved when converting an aberration map into a prescription for corrective lenses or refractive surgery. One of the most important factors is the

correction factor for the eye's chromatic aberration. Objective aberrometers typically use infrared light, for which the eye has low refractive power relative to visible light. Optical models of chromatic aberration across the visible spectrum can be extrapolated to estimate the difference in optical power of the eye between the measurement wavelength and some visible wavelength, but it is unclear what wavelength should be chosen as a reference. Furthermore, since only one wavelength can be in-focus at a time, some method is needed to factor in the relative contribution of all wavelengths, each with a different amount of defocus and a different visibility (the product of source radiance and human spectral sensitivity), to the perception of best-focus. Thus, a method for adjusting a refractive prescription which takes into account the varying refractive qualities of different wavelengths of light is desirable.

Another aspect of ocular chromatic aberration is that the eye's fundus, which reflects light used in objective aberrometry, is a "thick mirror" that makes the eye appear to vary in length depending on the wavelength of light. Infrared light penetrates further into the fundus, making the eye more myopic compared to the situation when visible light is used. Since objective aberrometers typically employ infrared light for measurement, a compensation for this reflective aspect of chromatic aberration is necessary in addition to the compensation for refractive chromatic aberration described above.

A different kind of problem is to incorporate into the method the refractionist's rule "maximum plus to best visual acuity." According to this clinical rule, the spherical component of myopic eyes is deliberately under-corrected in a prescription. The amount of under-correction is not enough to diminish visual acuity, but it is sufficient to minimize unnecessary accommodation and to maximize the usable depth of focus (DOF) at distance and near. These twin goals are achieved by prescribing a spherical lens power that is slightly less negative (in the

case of myopia) or slightly more positive (in the case of hyperopia) than the lens required to make the retina conjugate to infinity. The prescribed lens conjugates the retina with the hyperfocal point, which is defined as the nearest point the retina can focus on without reducing visual performance. Consequently, the eye is left in a slightly myopic state, compared to an optimum correction that would place the retina conjugate to infinity. Therefore, the typical methods of prescriptive calculations do not take into consideration those realities that opticians incorporate through subjective approximation and trial and error, creating a need in the industry.

Another approach to interpreting aberration maps is to use the map to compute the retinal image of fundamental visual objects, such as a single point of light or sinusoidal gratings. However this does not necessarily reduce the dimensionality of the problem because the image of a point object is itself a complicated entity, the point-spread function (PSF). Likewise, the description of the image of grating object is a complex-valued optical transfer function (OTF) that can be difficult to interpret. In either case there is a need for further data reduction that reduces the PSF or OTF to a single number, such as the Strehl ratio or cutoff spatial frequency, that is indicative of the optical quality of the eye.

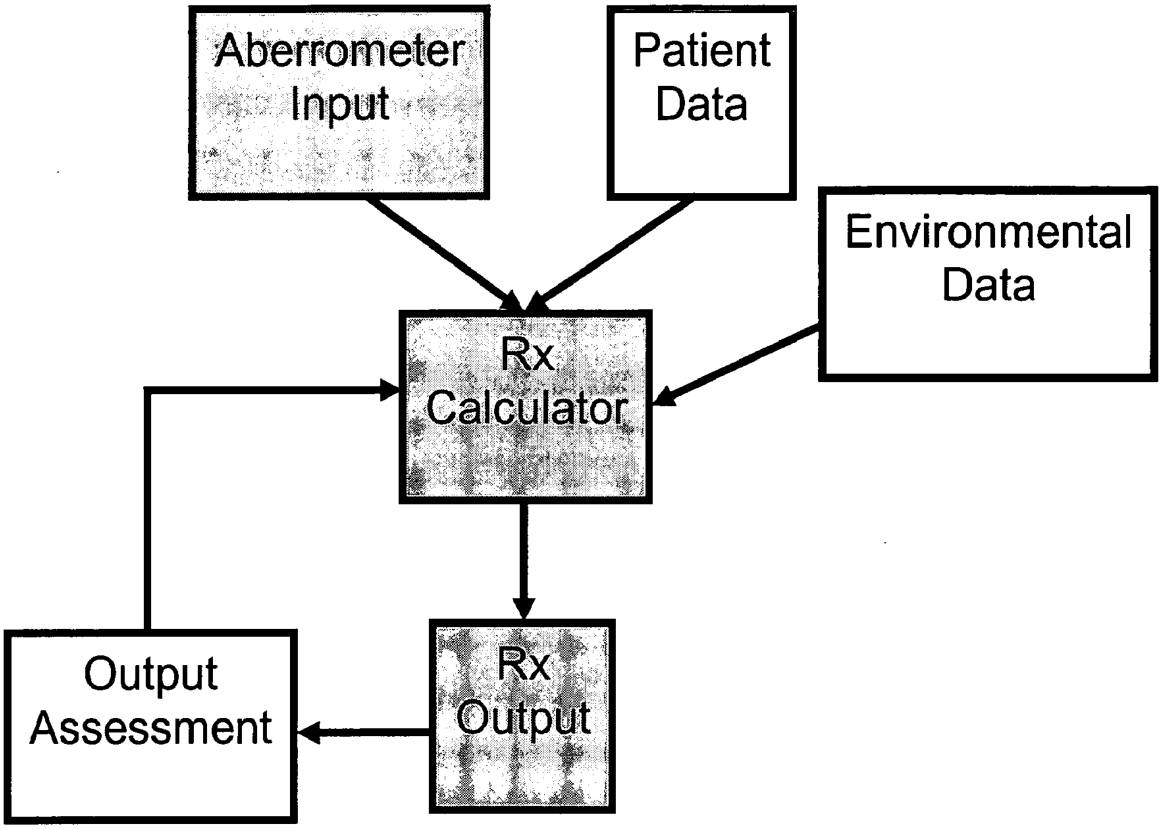
Additionally, an optimized ocular refractive prescription must take into consideration more than an optimized optic refraction. For example, a wise clinical optician must take into consideration patient data, environmental data, and apply clinical judgment to adjust the optically optimized prescription. Failure to include these inputs will lead to numerous unacceptable prescriptions. For instance, the patient's history might state that she has never worn glasses. Depending on the magnitude and type of prescription needed, a full prescription calculated using only aberrometry as an input may have a high probability of being totally unacceptable to the patient. This is despite the fact that a prescription derived simply from aberrometric data might

be optically best. An example is a high hyperopic or astigmatic correction. Such a correction is generally titrated slowly to a full correction over time. Another example has to do with their general health. If the patient is diabetic and is not under control, the prescription will not be stable. Unless the refractive error is relatively large it is much better not to prescribe anything until they disease is under control.

Next there are several environmental factors that influence the final prescription. One of the major factors influencing the actual power of the prescription is the distance at which the patient wants to have optimal vision. Are these computer glasses, piano glasses, distance glasses, etc? Then there are the purposes of the prescription. Are they safety glasses, sunglasses, contact lenses, etc.? Another critical element is an assessment to refine calculations based on historical experience with similar patients. Each of these steps often requires subjective decisions based upon clinical experience by the optician, and must be made after or in addition to the calculations for optical optimizations based upon aberrometric maps. Therefore, a method or system incorporating these clinical and patient considerations is desired.

Additionally, an automated method or system to perform this task in a more accurate fashion utilizing less computing power is further desired.

# Fig. 1: Data Flowchart for Method and System




Referring to Fig. 1, a system and method for calculating a refractive prescription for an individual's needs, a flow chart for data input and integration for calculation is shown. As can be seen, the path to the final prescription (Rx) with only aberrometric input is illustrated by the darkened boxes, representing one embodiment. An optically optimized refractive prescription can be determined through this pathway alone, optimized for a specified working distance as further described in appendices A and B.

However, clinical wisdom and optometric and ophthalmic practice indicate that this is an incomplete assessment. Therefore, another embodiment includes, in addition to the aberrometric

data, the use of patient data in the form of medical and other significant data indicating the patient's health, past optometric and ophthalmic experience and preference. Other important factors include age of the patient, habitual prescription, type of correction (glasses, contact lenses, refractive surgery, IOLs, inlays, etc.). Further environmental data is included, such as the manner in which the patient typically uses her eyes, what type of working environment the patient finds herself in, and standard clinical judgments reduced to data form. The result is a more complete system that makes judgments on multiple inputs as illustrated above, as opposed to simply using aberrometric optimizations.

Yet another embodiment of the method may take the form of steps outlined below:

**Step 1.** Acquire aberrometry data as input. This includes:

a. Vector of Zernike coefficients defining a monochromatic aberration map

b. Pupil radius

c. Wavelength of light

d. Select a method to use for the purpose of optimizing optical quality.

i. this may take the form of any one of thirty-three (33) methods described in Appendices A and B.

**Step 2.** Eliminate the bulk of the spherical and cylindrical refractive errors by nulling the second-order Zernike coefficients. An alternative method would be to null the second-order Seidel coefficients. The result is called a "higher-order aberration map."

**Step 3**. Implement one of 33 methods for choosing a prescription (described more thoroughly in Appendices A and B.

a. If the optimization method is the one called "RMS", the prescription is computed directly from the value of the second-order Zernike coefficients.

b. If the optimization method is the one called "CURVE" (described as the curve-fitting method in Appendices A and B), the prescription is computed directly from the values of the second-order and $4^{th}$-order Zernike coefficients.

c. Otherwise, perform three separate "through-focus" calculations on the higher-order aberration map to obtain the values of second-order coefficients that separately maximize the chosen metric of optical quality. These through-focus calculations are performed by selecting a value of one of the second-order coefficients from a pre-selected set of values that correspond to clinically-meaningful (e.g. 1/8 Diopter) steps of focus (Z2\0), ortho-astigmatism (Z2\+2), or oblique astigmatism (Z2\-2). The prescription is the sum of the optimum values so obtained and the original second-order aberration coefficients that were nulled in step 2.

Additionally, various permutations or variations upon the above-mentioned embodiment can be performed. This includes:

1. Choosing the prescription based on some combination of the above outcomes.
2. Optimizing optical quality for polychromatic light for any given source spectrum.
3. Defining a range of prescriptions that are functionally equivalent based on measurements of depth-of-focus for each of the 3 second-order aberrations.

4. Modifying the prescription to take into account inputs from environment data, ancillary patient data, outcome assessment.

Another embodiment of the invention comprises a software program capable of performing prescription calculations from aberrometer input. These calculations can be made using one of the thirty-three metrics or methods described in Appendices A and B. Additionally, one embodiment may take the organizational structure, and/or utilize the programs indicated below.

ORGANIZATIONAL STRUCTURE OF SOFTWARE

WavefrontRx

```
walkFolders
WATSRx
    metricNames
    Zc2Rx
        metricNames
        Zernike2Fourier
            Znorm
                mode2index
        Fourier2Zernike
            Znorm
        QualityMetrics
            metricNames
            Zc2psf2otf
                zernikeR_15
                zernikeR_21
                zernikeR_28
                zernikeR_36
                zernikeR_45
                zernikeR_55
                zernikeR_66
            WaveMetrics
                XY2Radial
                interp1LNT
                curvature
                    gradient2
            PSFMetrics
                somb2d
                    somb
                Gaussian
                get2DNeuralPSF
                    getNeuralPSF
                        getNeuralCSF
                max2D
                xcorr2
                Entropy
```

**centroi2**

**OTFMetrics**

**DiffractionMTF**

**AreaByNeuralLimitv3**

**getNeuralCSF**

**RadialAverage**

**XY2Radial**

**getNeuralCSF**

## KEY OPTICS PROGRAMS

**WavefrontRx** - a script to predict refractions for a batch of data files containing WAT data structures

**WATSRx** - function to find the best refraction of an eye from a set of aberration maps defined by a matrix of Zernike vectors

**Zc2Rx** - find the best refraction of an eye from an aberration map defined by a vector of Zernike coeffs. Based on the concept of successive elimination described in JOV ms 'Accuracy and Precision of Objective Refraction from Wavefront

**QualityMetrics** - compute metrics of optical quality from a given spectrum of Zernike coefficients

**Zc2psf2otf**: optical transfer function (OTF) and point-spread function (PSF) from Zernike aberration coefficients

**WaveMetrics** - metrics of wavefront quality based on Marechal (rms), Rayleigh (absolute), and Klein (slope) criteria

**curvature** - compute various curvatures of wavefront

**PSFMetrics** - compute measures of quality for a Point Spread Function

**OTFMetrics** - compute several measures of quality for an Optical Transfer Function

**AreaByNeuralLimitv3** - find cutoff spatial frequency and area under rMTF

**ZernikeR** Evaluate Zernike circle polynomial of modes 1-66 for sample points specified in rectangular coordinates. To enhance computational speed, parent program was subdivided into Zernike_XX, where XX = maximum number of modes to be evaluated.

Additionally, another embodiment may include combinations or permutations of these programs, or may include the ability to utilize other patient data or environmental data. Further descriptions of the present invention are found in Appendices A and B attached hereto.

## Claims

What is claimed is:

1. A method for optimizing a subjective refractive prescription comprising the steps of:
   a. obtaining aberrometric data;
   b. eliminating a bulk of spherical and cylindrical refractive errors; and
   c. implementing a method for choosing a prescription.

2. The method of Claim 1 wherein the spherical and cylindrical refractive errors are eliminated by nulling second-order Zernike coefficients.

3. The method of Claim 1 wherein the spherical and cylindrical refractive errors are eliminated by nulling the second-order Seidel coefficients.

4. The method of Claim 1 wherein the spherical and cylindrical refractive errors are determined by three sequential, through-focus calculations. These calculations identify, in turn, the three orthogonal, second-order Zernike coefficients that optimize the eye's optical quality.

5. The method of Claim 1 wherein the second-order Zernike coefficients that optimize the eye's optical quality are adjusted to take into account additional patient data referring to, but not limited to, age, occupation, health, and patent preferences.

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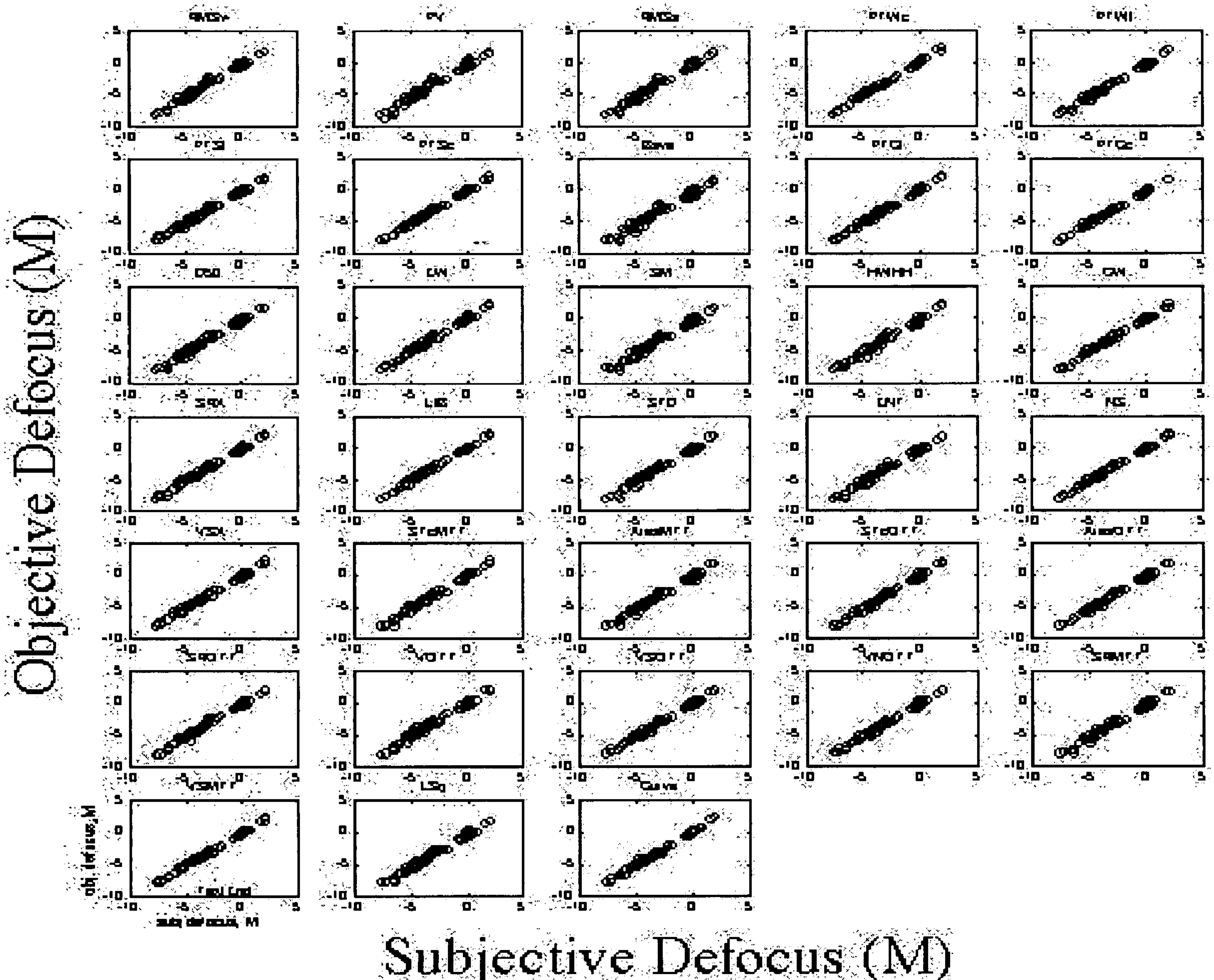




Figure 1

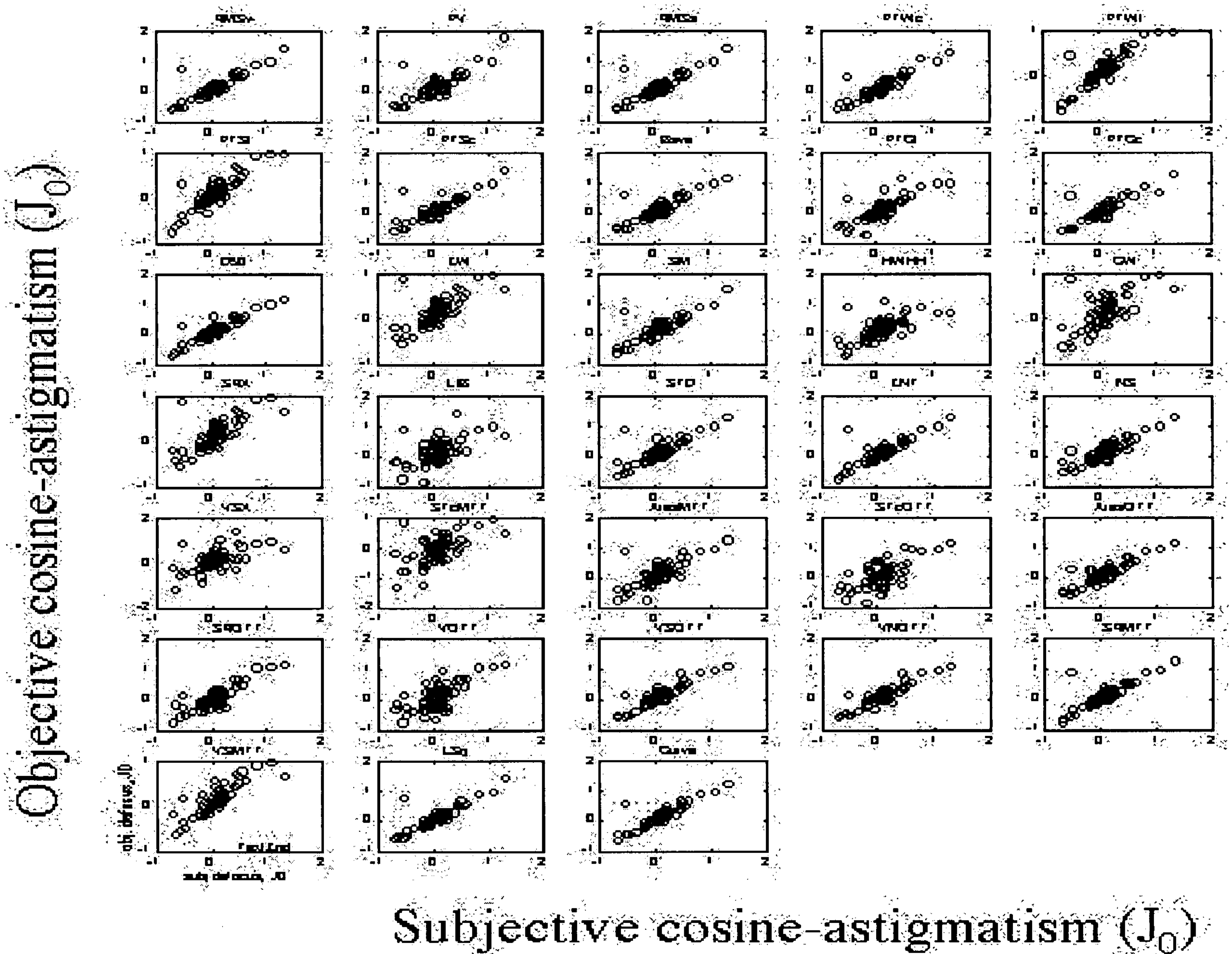
Objective cosine-astigmatism ($J_0$)
Subjective cosine-astigmatism ($J_0$)



Figure 2

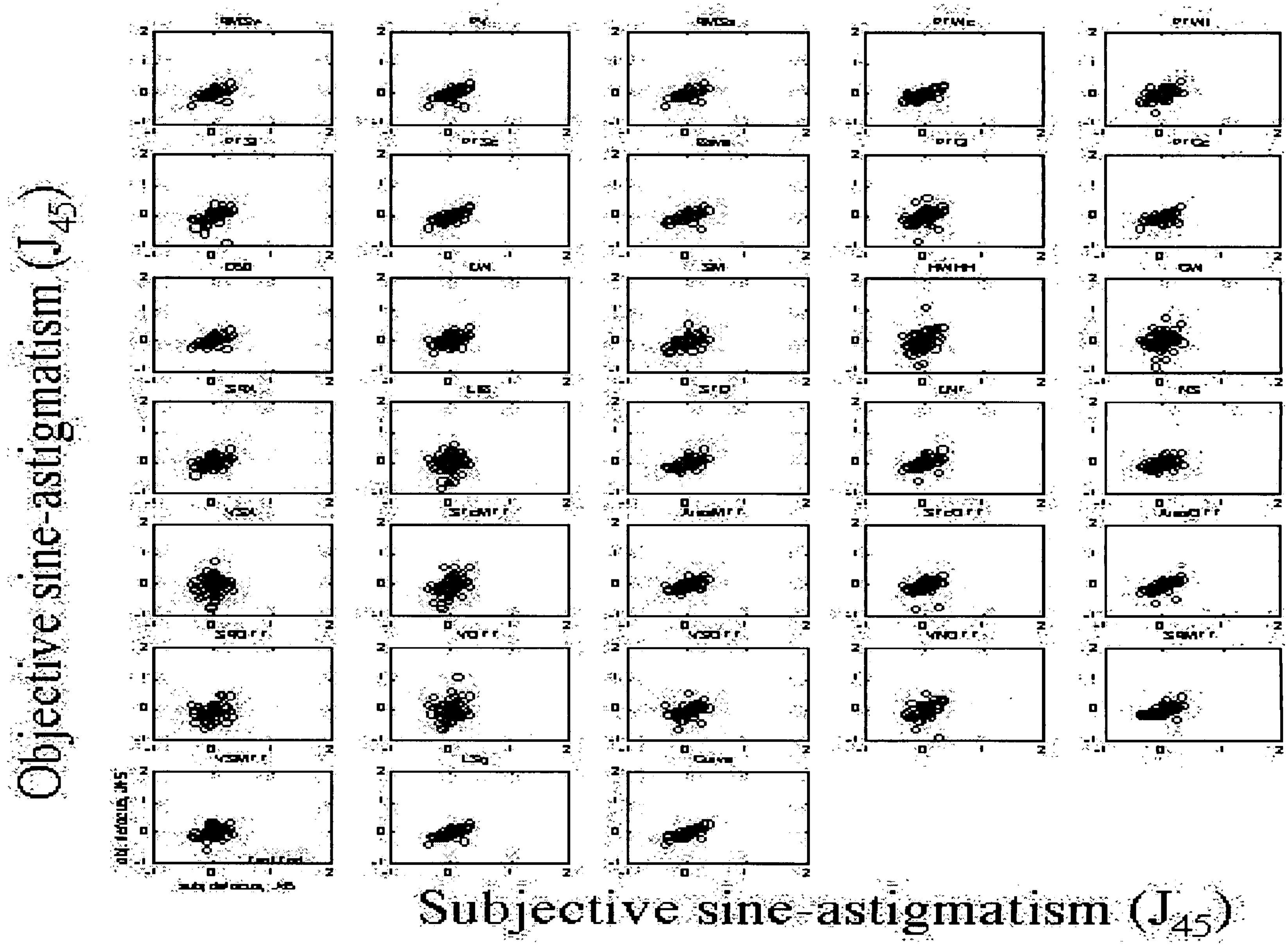


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Figure 3

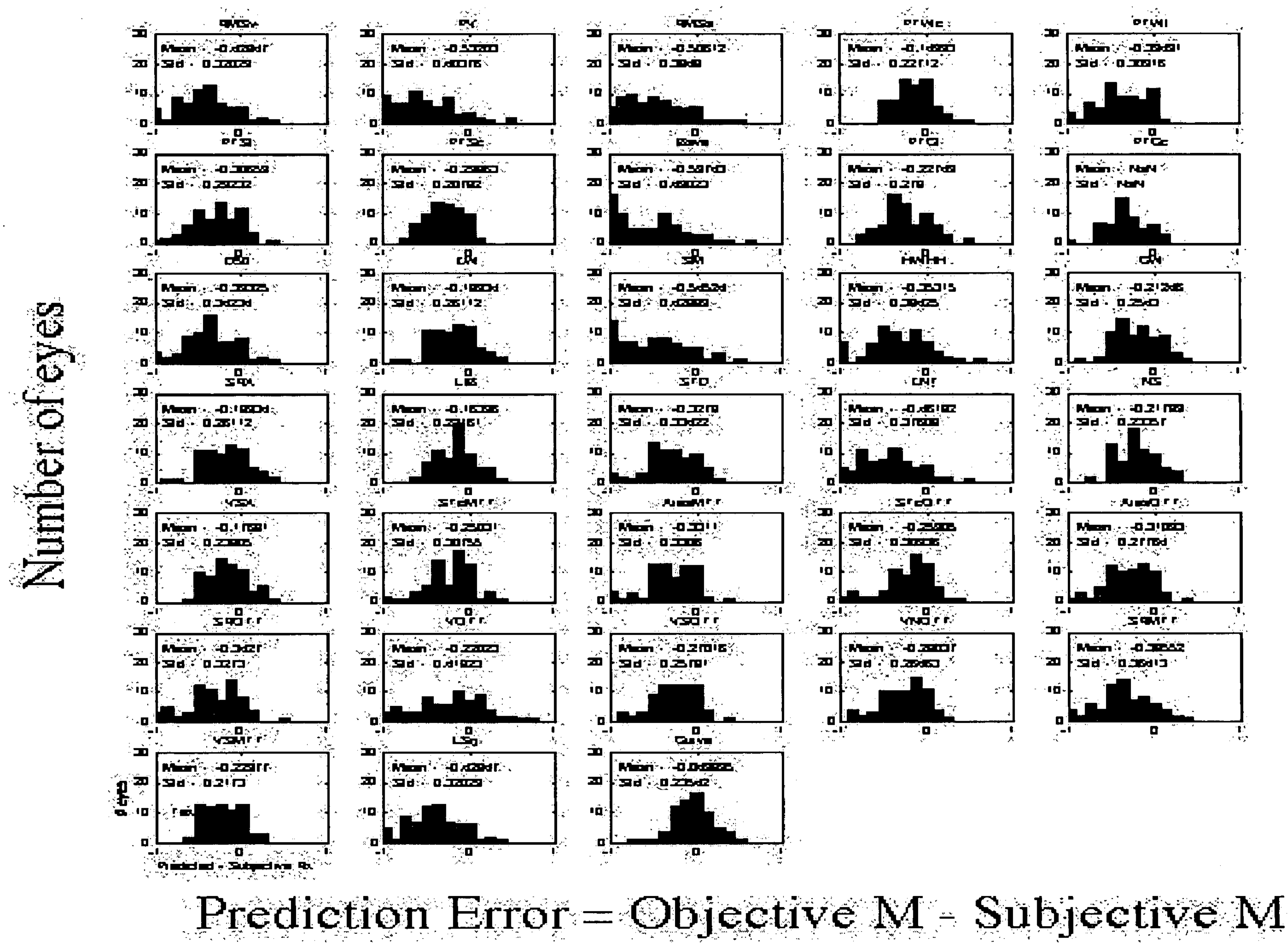




Figure 4

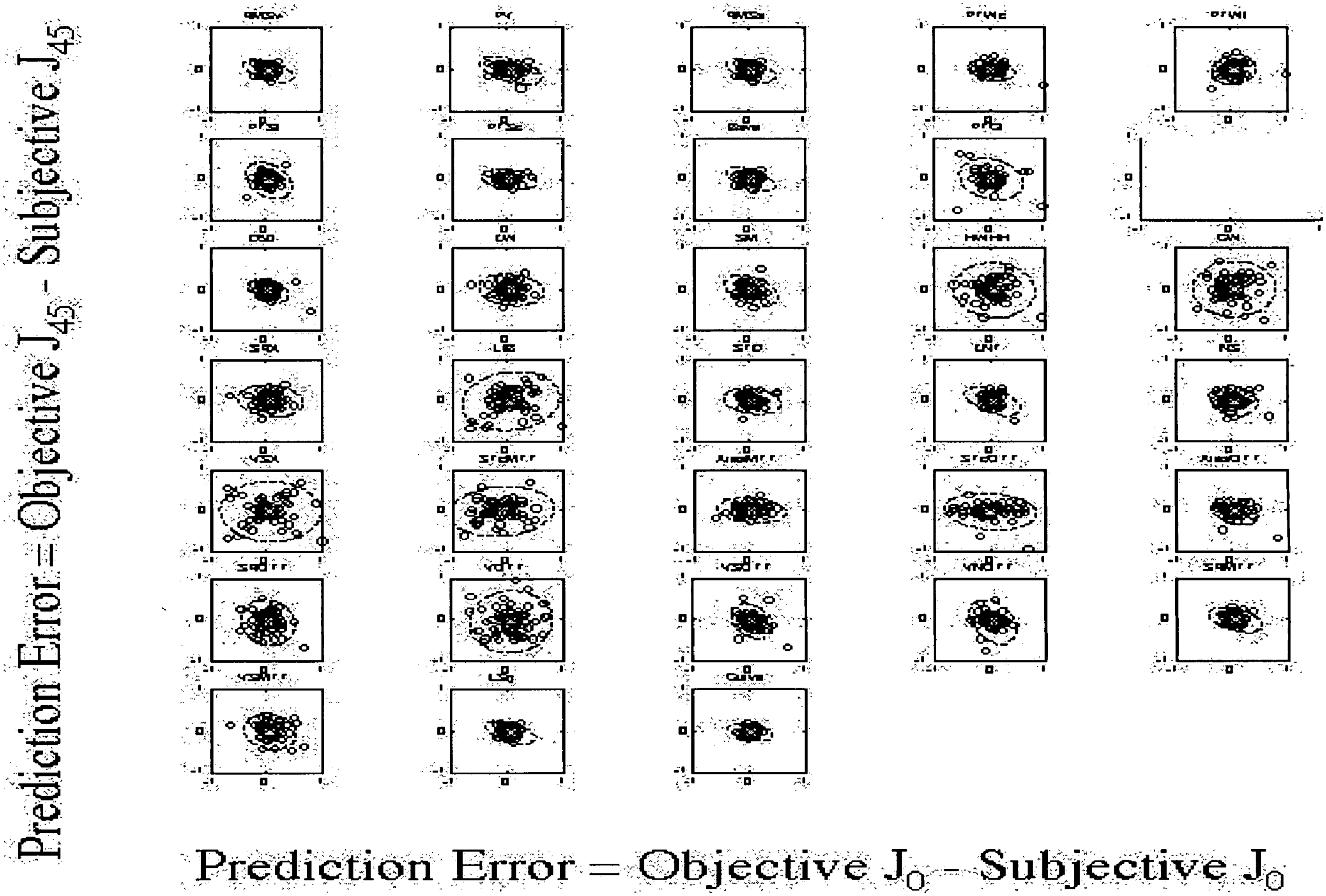
Prediction Error = Objective $J_{45}$ - Subjective $J_{45}$
Prediction Error = Objective $J_0$ - Subjective $J_0$

Figure 5

PTO/SB/01 (03-01)(Amended by Customer pursuant to MPEP § 601.02)
Non-Amended Version Approved for use through 10/31/2002. OMB 0651-0032
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**DECLARATION AND POWER OF ATTORNEY FOR UTILITY OR DESIGN PATENT APPLICATION (37 CFR 1.63)**

☒ Declaration Submitted with Initial Filing OR ☐ Declaration Submitted after Initial Filing (surcharge (37 CFR 1.16(e)) required)

| | |
|---|---|
| Attorney Docket Number | P00873-US-00 |
| First Named Inventor | THIBOS, Larry N. |
| *COMPLETE IF KNOWN* | |
| Application Number | / |
| Filing Date | |
| Group Art Unit | |
| Examiner Name | |

**As a below named inventor, I hereby declare that:**

My residence, mailing address, and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

SYSTEM AND METHOD FOR OPTIMIZING CLINICAL OPTIC PRESCRIPTIONS

*(Title of the Invention)*

the specification of which

☒ is attached hereto

OR

☐ was filed on (MM/DD/YYYY) [ ] as United States Application Number or PCT International

Application Number [ ] and was amended on (MM/DD/YYYY) [ ] (if applicable)

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR 1.56, including for continuation-in-part applications, material information which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby appoint the practitioners at Customer Number 22446 as my/our attorney(s) or agent(s) to prosecute the application identified above, and to transact all business in the United States Patent and Trademark Office connected therewith.

I hereby claim foreign priority benefits under 35 U.S.C. 119(a)-(d) or (f), or 365(b) of any foreign application(s) for patent, inventor's or plant breeder's rights certificate(s), or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below, by checking the box, any foreign application for patent, inventor's or plant breeder's rights certificate(s), or any PCT international application having a filing date before that of the application on which priority is claimed.

| Prior Foreign Application Number(s) | Country | Foreign Filing Date (MM/DD/YYYY) | Priority Not Claimed | Certified Copy Attached? YES | NO |
|---|---|---|---|---|---|
| | | | ☐ | ☐ | ☐ |
| | | | ☐ | ☐ | ☐ |
| | | | ☐ | ☐ | ☐ |
| | | | ☐ | ☐ | ☐ |

☐ Additional foreign application numbers are listed on a supplemental priority data sheet PTO/SB/02B attached hereto:

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# DECLARATION AND POWER OF ATTORNEY Utility or Design Patent Application

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. 1001 and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

| | | | |
|---|---|---|---|
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| Inventor's Signature Arthur Bradley | | | Date |
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| City Bloomington | State IN | ZIP 47401 | Country USA |

☒ Additional inventors are being named on the 1 supplemental Additional Inventor(s) sheet(s) PTO/SB/02A attached hereto.



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| DECLARATION | ADDITIONAL INVENTOR(S) Supplemental Sheet Page 3 of 3 |
|---|---|

| | | | |
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| **Name of Additional Joint Inventor, if any:** | ☐ A petition has been filed for this unsigned inventor | | |
| Given Name (first and middle [if any]) | Family Name or Surname | | |
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| **City** Kingwood | **State** TX | **ZIP** 77339 | **Country** USA |

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| **Name of Additional Joint Inventor, if any:** | ☐ A petition has been filed for this unsigned inventor | | |
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| | | | |
| **Inventor's Signature** | | | **Date** |
| **Residence: City** | **State** | **Country** | **Citizenship** |
| **Mailing Address** | | | |
| **Mailing Address** | | | |
| **City** | **State** | **ZIP** | **Country** |

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|---|---|---|---|
| **Name of Additional Joint Inventor, if any:** | ☐ A petition has been filed for this unsigned inventor | | |
| Given Name (first and middle [if any]) | Family Name or Surname | | |
| | | | |
| **Inventor's Signature** | | | **Date** |
| **Residence: City** | **State** | **Country** | **Citizenship** |
| **Mailing Address** | | | |
| **Mailing Address** | | | |
| **City** | **State** | **ZIP** | **Country** |



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